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**13. ABSTRACT** ***(Maximum 200 Words)***

While there have been recent advances in the development of complementary approaches to breast mammography, breast cancer remains a prevalent and devastating disease. For the most part new advances fail to provide real-time, large field of view, high-resolution approaches to breast imaging where both early detection and subsequent management of breast disease are primary targets. The purpose of this three-year study is to evaluate a promising approach to breast imaging using a diffractive energy imaging technology developed by Advanced Diagnostics, Inc. Progress in the first year lead to methods for evaluating the changes to a prototype system and collecting breast imaging data. This report describes progress made during the second year of the study to implement these methods. Reliable and repeatable procedures for quantifying system performance and collecting breast imaging data will be discussed. The results of data collected from a group of individuals with normal breast anatomy, along with preliminary results from simulated breast biopsies will also be presented. These results continue to provide valuable information to the ADI's image quality improvement program and have had a positive impact on system development.

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## Table of Contents

## INTRODUCTION

The *primary objective* of this study is to evaluate the suitability of Optical Sonography* for the detection and characterization of breast disease. Optical Sonography or Diffractive Energy Imaging is a method of ultrasound imaging that utilizes a coherent laser beam to illuminate an interference pattern generated from an acoustic wave transmitted through an object and a reference wave. The image is produced from the perturbations in both phase and amplitude of the acoustic beam (dependent on the acoustical properties of the object) at the surface of a detector. Since reconstruction is performed optically, image formation is produced in real-time. A more detailed review of the science and history of this technology is provided in the literature.[1-10] The *purpose and scope* of this study in its first year was to alter a prototype system in preparation for breast imaging, and to develop methods for evaluating these system changes and the resultant images. In addition, various procedures for breast imaging were tested and methods for image enhancement were explored. In the most recent year of the study the purpose and scope was to implement the methods developed during the first year. This included the implementation of formalized system metrics and breast imaging procedures, along with preliminary image enhancement efforts. The results of data collected from a group of individuals with normal breast anatomy, along with preliminary results from simulated breast biopsies completed on biopsy training phantoms will also be presented.

*Note: While the term, Optical Sonography, will remain in the title of this project, Advanced Diagnostics, Inc. (ADI) wishes to introduce, *diffractive energy imaging (DEI)*, adopted by the Company as a term more descriptive of our technology's strength. DEI will be used throughout this report.

## BODY

As part of the yearly update a review of the prototype system modifications will be presented along with a review of progress on Year 2 tasks.

Prototype System Modifications

The Optical Sonography alpha prototype medical imaging device modified for breast imaging (Figure 1) was installed at the University of Washington during Year 1 of the project, and was used to collect data on phantoms, to help establish standardized metrics, and to help define preliminary imaging procedures. These evaluations prompted some additional device modifications that were implemented during Year 2. Redesign focused on the

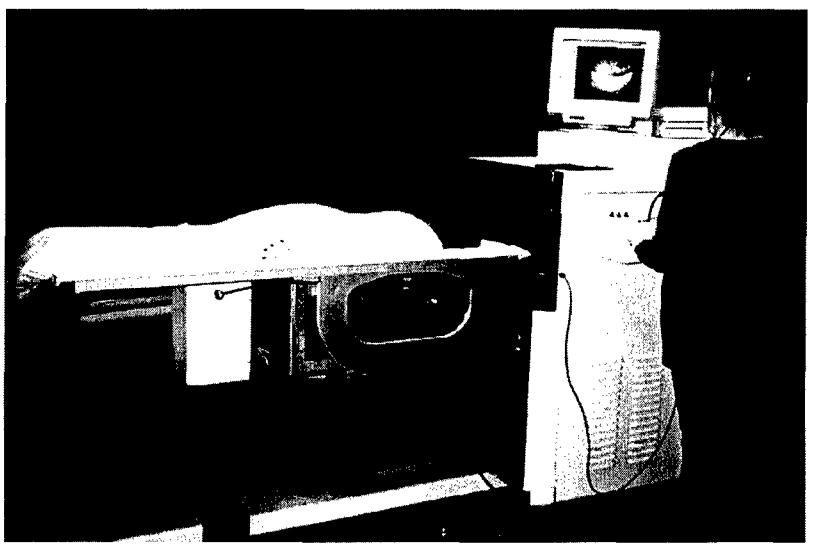

Figure 1. Alpha prototype designed specifically for breast imaging.

patient interface where the objective was to increase access to the chest wall and axilla. Additional views of the breast were achieved through patient table rotation and translation (e.g., translation in 3 planes for more precise placement of the breast within the sound field, and rotation of the patient about the vertical axis for cranial-caudal and medial-lateral imaging or any oblique position). As a result of these design changes a beta system was completed and is shown in Figure 2.

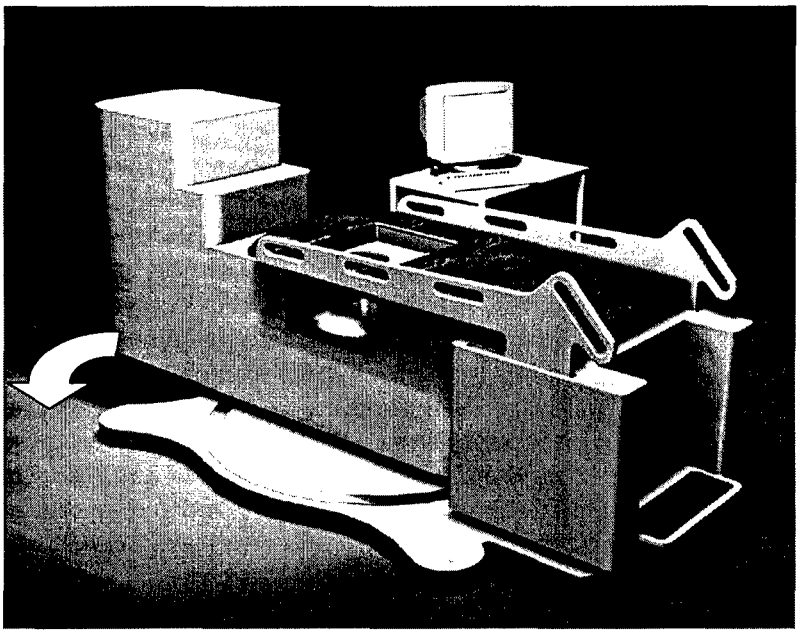

Figure 2. Beta prototype designed to achieve translation of the patient and rotation of the sound beam about the target anatomy

Subsequent evaluation of this beta stage prototype underscored several important issues. First, the rotational feature provided access to the breast from any position in a 200 plus degree arc about the breast. But, it also increased the system footprint unrealistically, hindering installation in a typically-sized medical imaging room. And, in fact, the newer prototype could not be installed at the University of Washington, our consultant's site, due to room size limitations. While reducing the footprint was possible, the true revelation was that a system producing image slices much like a CT scanner has all the necessary volumetric data inherent in the image set. In other words, there would be image information redundancy in sets of image slices acquired at various rotational positions. The decision was made to eliminate the rotation feature. In addition to reducing the overall system footprint to fit into an 8' x 8' room, the proposed medial-lateral imaging approach increases access to the patient chest wall by lowering the patient between the source transducer housing and the lens tube. In previous designs the patient had to lie over the transducer housing and acoustic lens tube in the cranial-caudal position, thus reducing the ability to lower the patient into the water bath and sound beam. This latest pre-production design concept is shown in Figure 3. A unit will be ready for installation at

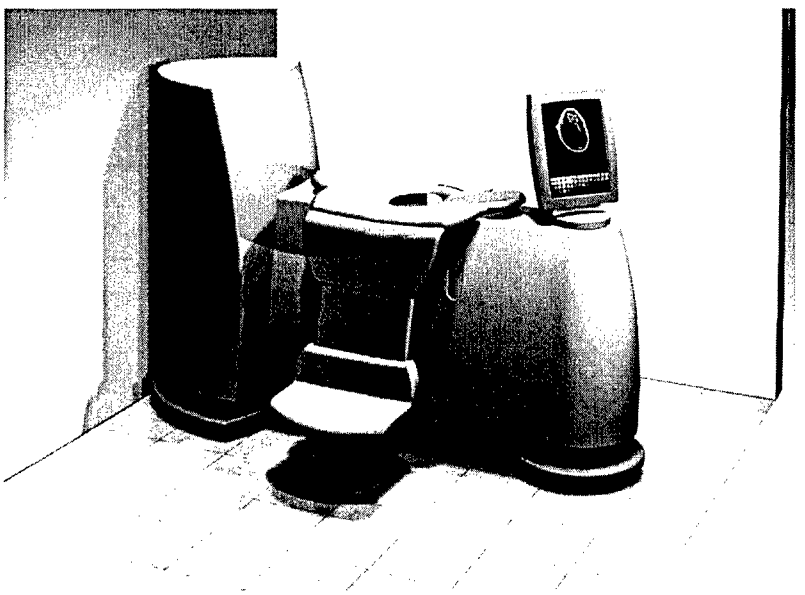

Figure 3. Pre-production unit design concept

our consultant's site during the first quarter of FY02. In the interim, images will be provided to the University of Washington consultants from the larger beta prototype located at another facility. This approach will provide ADI consultants with the most recent images, and eliminate any potential changes or delays to the approved Statement of Work.

YEAR 2: Review of Progress by Task

In Year 2 of the BCRP study, Tasks 7 through 12 and Tasks 18 and 19 were completed. Progress on each of these tasks will be discussed in order.

*Task 7* included the implementation of standardized metric procedures for ensuring image quality control. These procedures were formalized as ADI Inspection/Test Procedure #02000-00 and automated to the extent that software evaluation packages have been developed to accept image data and provide computed results. These procedures have been used to track performance of clinical systems in the field and as a tool to evaluate proposed changes to future system designs. Most recently, the metrics procedure was used in an Image Quality Improvement Program where proposed changes to the beta prototype system were evaluated systematically component by component. The metrics provided a quantitative assessment of the system modulation transfer function, effective size of the field-of-view, spatial resolution across the effective field of view, contrast resolution, high contrast event detection, and field uniformity. Several decisions on component modifications were made based upon the results of the metric data. Figures 4 through 6 provide several examples of developed metrics targets, images and results.

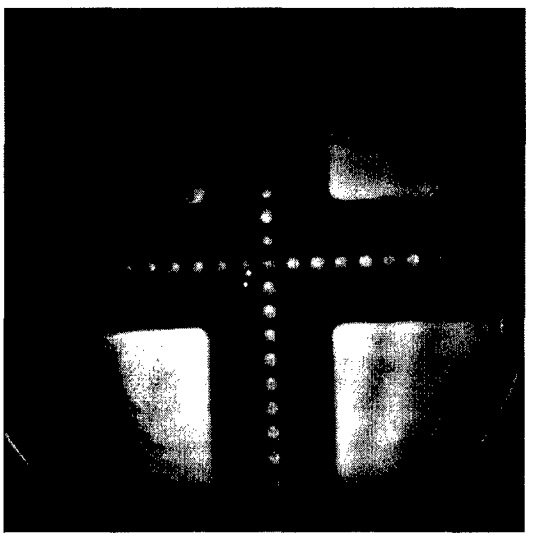

Figure 4. Field-of-view target

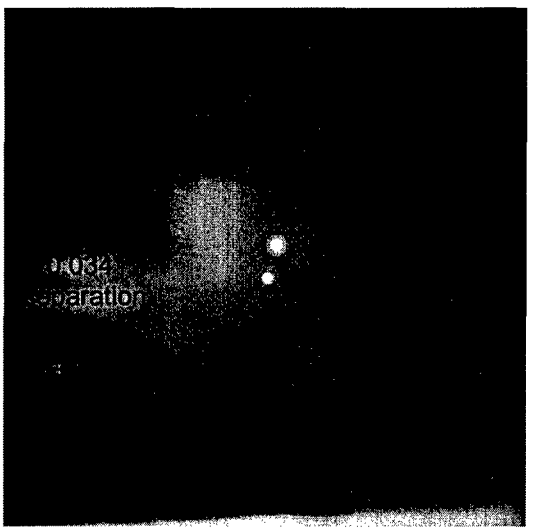

Figure 5. Spatial resolution target

Field of View (FOV) Target: The FOV phantom is a machined plastic target with a series of 0.12 in (3 mm) holes spaced 0.20 in (0.5 cm) apart center-to-center in both vertical and horizontal (Figure 4). The numbers of holes that appear in the image give an indication of the effective field of view. The transducer size, position and orientation; laser pattern size; and camera lens impact the size of this field of view where typically the peripheral field is the first to be reduced. Recent measurements have resulted in an FOV that is uniform vertically and horizontally measuring 10 cm by 10 cm, or an effective FOV of 78.5 $cm^2$.

Spatial Resolution Target: The spatial resolution target is a 2.5 in (6.35 cm) by 2.5 in (6.35 cm) delrin block, 0.25 in (0.64 cm) thick. The target has a series of hole pairs machined into the 0.64 cm thickness. The smallest hole pair includes 0.016 in (0.40 mm) diameter holes with center to center separation of 0.050 in (0.127 cm). Metrics evaluation focuses primarily on resolving the inside edge to inside edge separation on this smallest hole pair, which is 0.034 in (0.086 cm). While this block has been used successfully, there is a desire to eliminate a hole configuration that presents a curved surface with variation in depth from it's edge to its center.

Knife Edge Target: A knife edge target is used to obtain the system modulation transfer function (MTF). A software program has been developed and implemented which uses the knife edge image and a perpendicular bisecting routine to compute a resulting MTF at 3 locations along the length of the knife edge target. This is illustrated in Figure 6. Values obtained in this study show center MTF values at 1.3 line pairs/mm at 20% modulation and values in the image periphery at between 0.81 and 0.88 line pair/mm at 20% modulation.

Figure 6. Knife edge target with computed MTF

A final example of the targets developed to characterize system performance includes a phantom to detection small, high contrast objects (Figure 7). This phantom substrate material simulates breast material (measured sound speeds and attenuation of 1495 m/sec and 0.95 dB/cm/MHz, respectively) and measures 5 cm (2 in) in thickness along the sound path. The small, high contrast targets are sieved from hydroxyapitite crystals to simulate

calcifications. Optical microscopy is used to verify sieved sizes (Figure 8). The results show that diffractive energy imaging can begin to detect small targets in the range of 0.2 mm (.008 in) at typical imaging frequencies (frequency sweeping from 2.4 to 3.0 MHz).

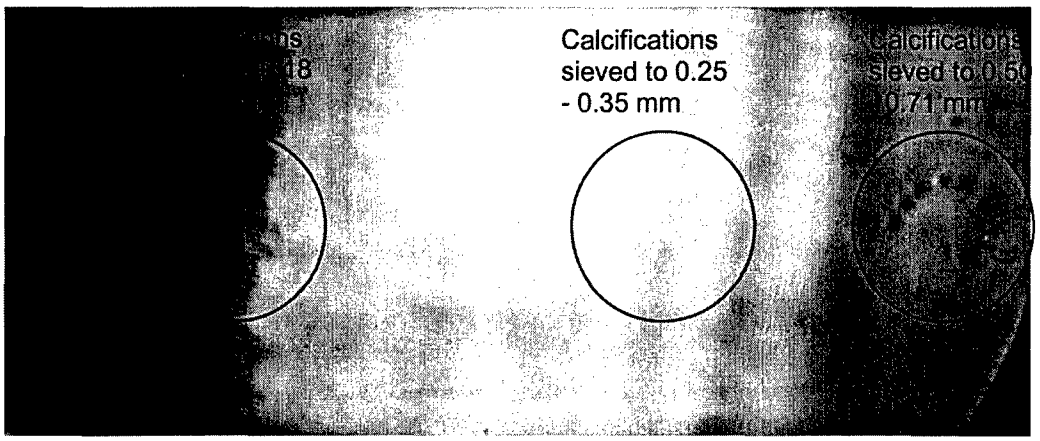


Figure 7. Simulated calcifications embedded in breast phantom illustrating the detection of small, high contrast objects.

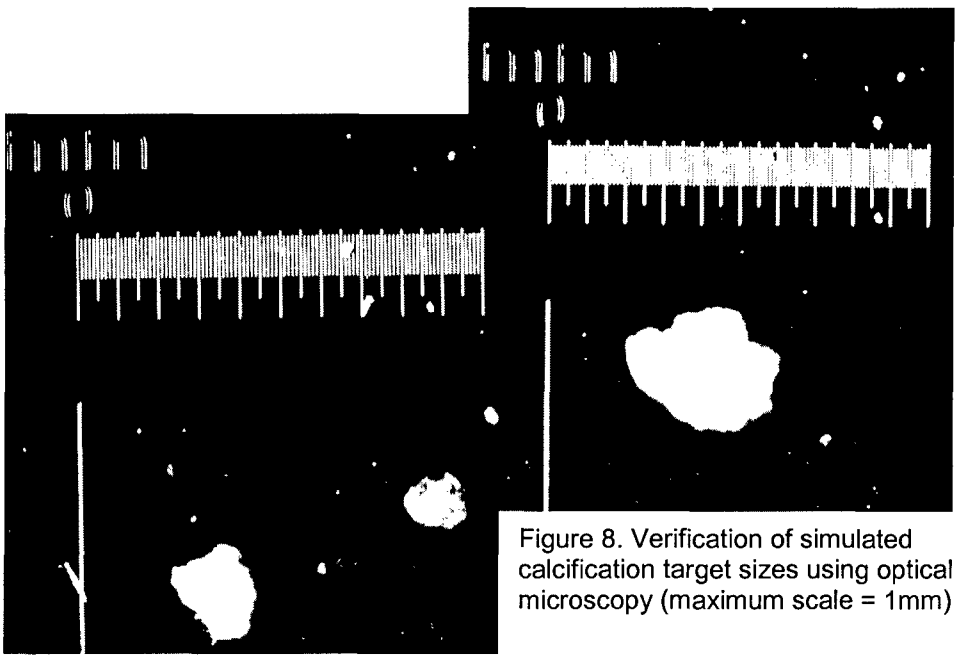

Figure 8. Verification of simulated calcification target sizes using optical microscopy (maximum scale = 1mm)

In *Task 8* a computer database for storage and retrieval of images was developed. This task was implemented in Year 1 of the study and discussed briefly in the first annual report. A procedure for collecting cineloops and autoscans of image slices with image data embedded in filenames and automatically generated text files, replaying sequences from the GUI, archiving data and retrieving archived 12-bit image data using ACDSee have been developed and implemented. Additional image data, patient information, and operator setting data will be incorporated into a more extensive database during the development of the ADI Acquisition Workstation. That development is beyond the scope of this project.

*Tasks 9 through 12* address the imaging of normal volunteers using the OS2000 Imager. Ten normal women volunteers with recent mammograms (< 1 month in all cases) from the University of Washington screening population were recruited for this study. Table 1 shows subject demographics relative to age, breast composition and breast size.

**Table 1. NORMAL VOLUNTEERS**

| Subject | Study No. | Age | Breast Imaged | Breast Composition | Breast Size |
|---|---|---|---|---|---|
| 1 | 050 | 79 | Right | Scattered Fibroglandular | S |
| 2 | 051 | 44 | Right | Heterogeneously Dense | S |
| 3 | 052 | 46 | Right | Heterogeneously Dense | S |
| 4 | 053 | 56 | Left | Heterogeneously Dense | M |
| 5 | 054 | 54 | Left | Extremely Dense | S |
| 6 | 055 | 81 | Right | Fatty | M |
| 7 | 056 | 49 | Left | Scattered Fibroglandular | M |
| 8 | 057 | 46 | Left | Scattered Fibroglandular | L |
| 9 | 058 | 51 | Right | Heterogeneously Dense | L |
| 10 | 059 | 76 | Right | Fatty | L |

As part of this task a breast imaging procedure was released as Work Instruction #02003-01. This procedure addresses practical issues associated with skin coupling, compression, patient position, system settings and patient tank water temperature.

As part of the development of these procedures, efforts in *Task 10* produced answers to questions centering on these practical issues. As an example, more compression (without inducing discomfort for the subject) rather than less compression diminished the amount of structure through the thickness being interrogated and reduced the acoustic intensity required to produce a clear image. The reaction from consulting physicians was that more compression reduced the number of confusing trabecular structures. However, upon closer examination using phantoms developed to explore cystic structures, concerns arose as to whether cysts in the breast would be compressed to a thickness smaller than the focal plane depth and be "lost" in the normal parenchymal structure physically located on either side of the cyst. This issue will be explored more in Technical Objective 3 (Year 3).

As an example of another practical issue, subject comfort related to water temperature was addressed. The desire was to have a product that could use tap water to lower operating costs and increase convenience by utilizing hospital tap water supply. The hypothesis was that dissolved gasses in solution at high line pressures in conjunction with available free air in the system would produce supersaturated water coming into the patient tank. The bubbles that come out of solution adhere to the vertical surfaces and breast skin surface when the pressure is reduced. Both dissolved air and the resulting bubbles have been shown to affect image quality. Several empirical tests were conducted and calculations were completed to determine the solubility of air in water at 1 atmosphere in the range of temperatures used. The conclusion was that water held in a buffer tank could be off-gassing during an imaging session and become the inlet water for the subsequent patient, thus allowing the dissolved gases to come out of solution. Additional testing was done to investigate the potential for image quality degradation from thermal gradients across the

barrier between the patient imaging tank and the detector tank. The percentage drop in intensity was not significant.

An autoscan of the breast can take up to 3 minutes and subject movement associated with respiration was a question. Women were asked to remain still during this data collection period and breathe normally. In almost all cases motion was not detected when using this procedure. Certainly exaggerated upper body movements and respiration can produce blurred images. Because the operator views the data collection in real-time however, recapturing the data can be completed immediately when patient movement is detected.

In *Tasks 10 and 11* data from the 10 normals were evaluated in conjunction with corresponding mammograms. Breast structures were identified and similarities in structure between the two imaging modalities were noted. The mammograms were key to the identification of many structures in the DEI images. Fatty tissue lobules, fibrous tissue compartmentalization, subcutaneous fatty areas, glandular tissue, and vascular and ductal structures were noted. Each subject was evaluated at 3 different display settings to determine optimal settings. Desired settings varied slightly depending on breast composition but generally a gamma setting of between 19 and 24 and a full range in grayscale (0 to 4095) were found to be optimal. One significant determination from this study was the importance of archiving the original 12-bit tiff images along with the scaled 8-bit version set by the operator. This provides complete image data sets available for post-processing while providing the desired operator settings for review and comparison during our image interpretation learning process.

Several images are provided as examples of normal breast tissue. Figure 9 illustrates the effort to identify structures with the normal breast. Figures 10 and 11 show comparisons between mammograms and DEI images for normal subjects representing the extremes in breast composition: extremely dense and fatty tissue.

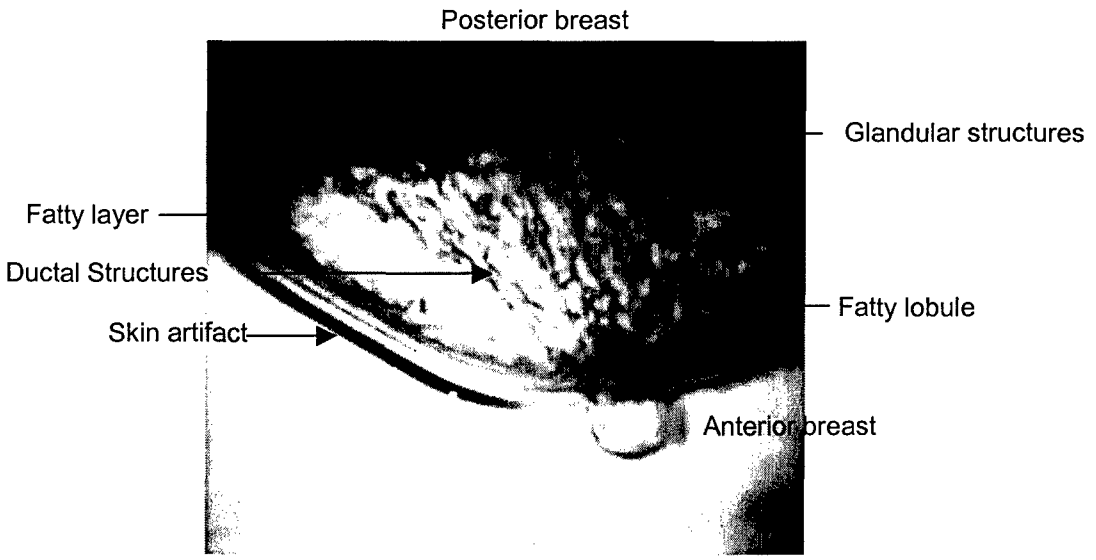


Figure 9. DEI image of normal subject: Lcc
View illustrating fatty area and breast structures


Figure 10a. Mammogram of normal subject with extremely dense breast composition (DEI image of same subject shown in Figure 10b)

Figure 10b. DEI image of normal subject with extremely dense breast composition (Mammogram of same subject shown in Figure 10a)

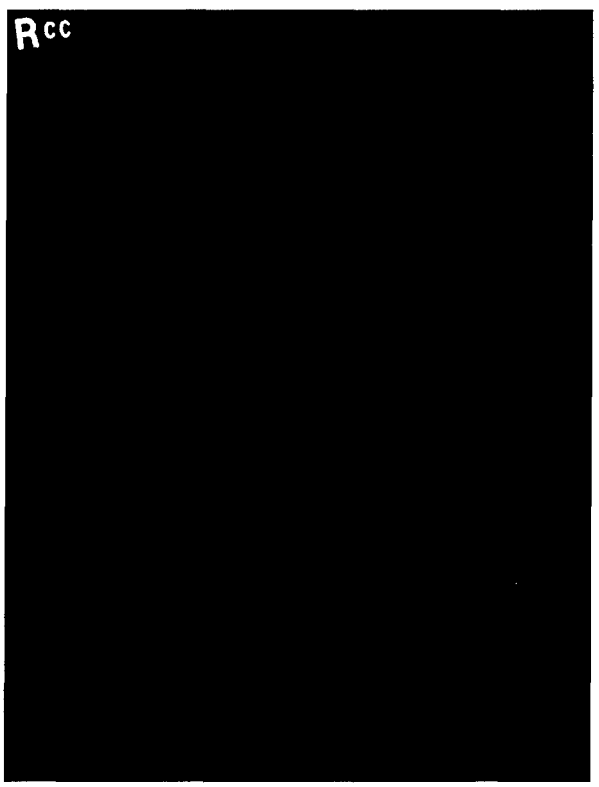


Figure 11a. Mammogram of normal subject with fatty breast composition (DEI image of same subject shown in Figure 11b)

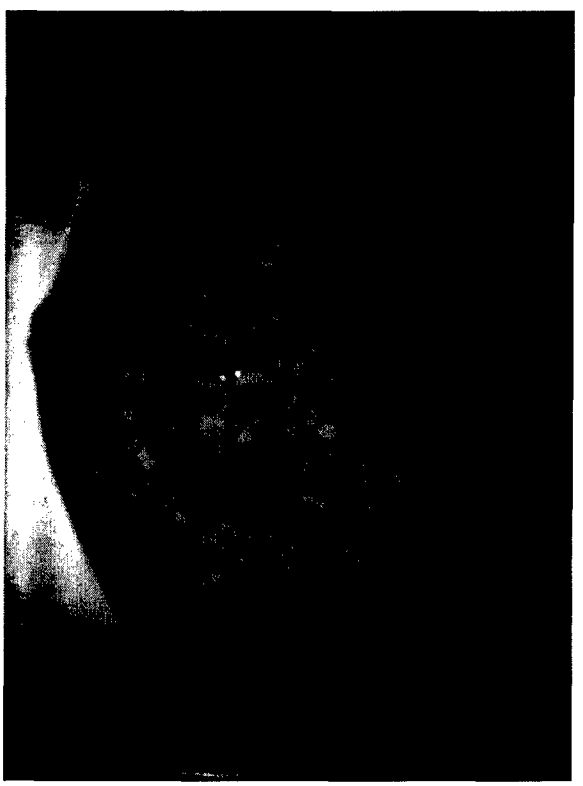

Figure 11b. DEI image of normal subject with fatty breast composition classified (Mammogram of same subject shown in Figure 11a)

*Task 12* addressed preliminary image processing activities. This task was addressed in greater detail in the Year 1 annual report, where several avenues for improving image quality were explored. The decision was made to limit the operator-controlled image processing to frame averaging, and brightness, contrast and gamma adjustments initially. These parameters have been incorporated into the GUI and are being actively used. In addition, several image quality activities were initiated as a separate effort. The results of these combines efforts are shown in the following images. Figure 12a illustrates an image of Normal Subject No. 058 as it appeared in the beginning of Year 2. Figure 12b shows Year 2 progress in image quality related to increased access to the posterior breast, more uniform image intensity, increased spatial resolution and a reduction in image artifacts.

Figure 12a. Normal Subject No. 058 prior to patient interface modifications, image quality improvements and post-processing

Figure 12b. Normal Subject No. 058 after patient interface modifications, image quality improvements and post processing

In addition, ADI developed a GUI-based Image Processing tool during Year 2. The tool provides the user with image I/O (Load, Save, Browse), selection (extraction of a Region of Interest), and several post-processing capabilities. The post-processing capabilities available to the user are:

- Brightness/Contrast/Gamma adjustment;
- Grayscale stretching;
- Edge enhancement;
- Inversion;
- Flip and rotate;
- Histogram equalization;
- Text insertion;
- Undo.

More specifically, the user can adjust the gray level look-up-table (i.e. Brightness/Contrast/Gamma) both numerically (using input boxes) and graphically (using the interactive LUT).

This tool will also allow the user to record his or her post-processing preferences together with diagnostic reports via a simple graphical interface. ADI will therefore be able to build a database of successful post-processing parameter sets with the corresponding diagnoses. The database will allow a correlation among post-processing parameter sets and diagnostic reports, and hence generate post-processing parameter sets customized to the most relevant clinical situations. In other words, there will be an optimal post-processing parameter set for each breast parameter combination (e.g. breast tissue composition/breast size/lesion type/lesion shape etc. employing the standard ACR BI-RADS breast imaging classification method). Figure 13 presents a Window concept for this post-processing software.

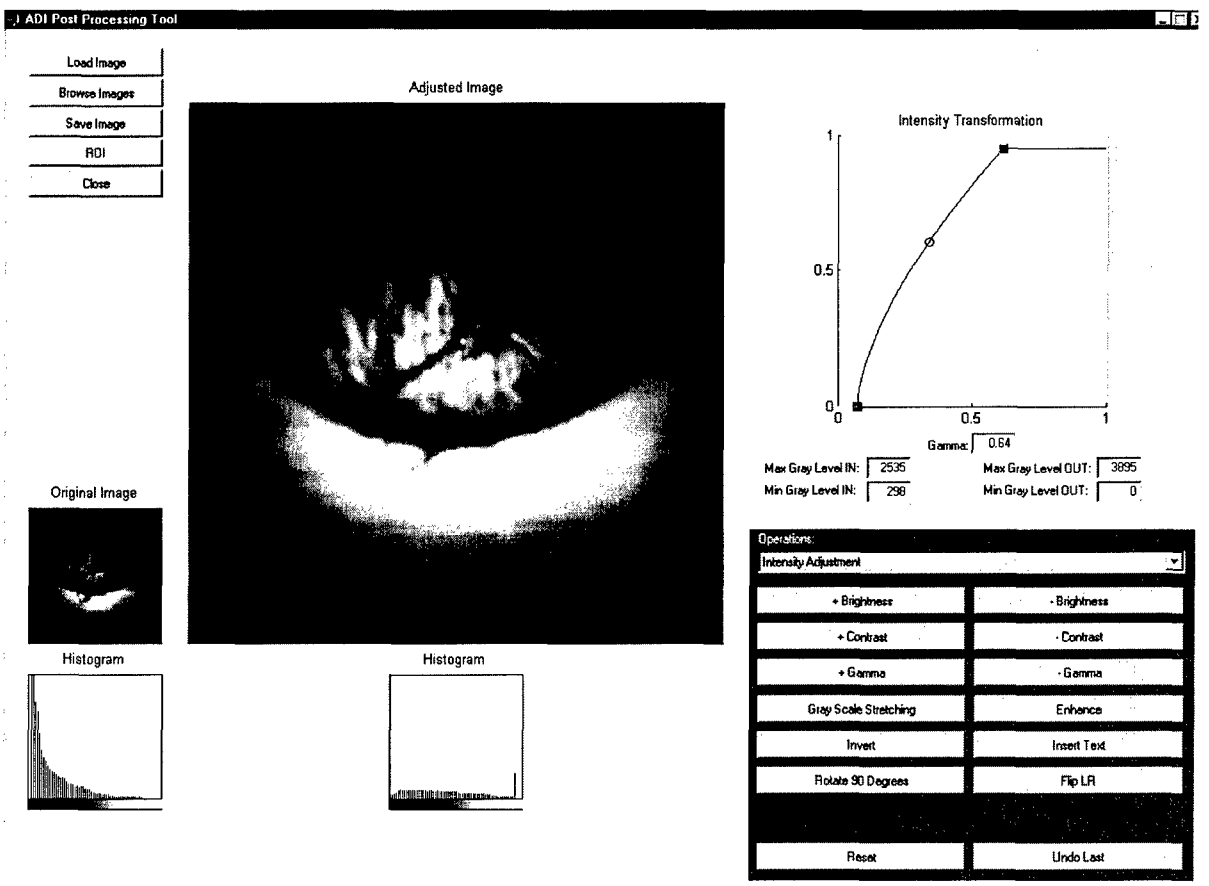


Figure 13. ADI Advanced Post-processing Tool Concept

In addition to the standard post-processing techniques, ADI is currently developing more sophisticated and customized pre-processing algorithms under a separate effort but based in part on findings from Year 1 of this study. They include:

1. Spatially Weighted Averaging
2. Flat-Fielding
3. Background Subtraction
4. Removal of Out-of-Focal-Plane Information
5. Deblurring

*Tasks 18 and 19* address the potential advantages of DEI in image guided surgical procedures, in this case, breast biopsy. In Task 18 contrast sensitivity and measurement of objects were addressed. While measures are still being undertaken to fully quantify contrast sensitivity, structures are located with sufficient certainty that the simulation of breast biopsy was completed. As a precursor to measurement and biopsy demonstration, a calipers feature was implemented. The associated GUI interface is illustrated in Figure 14. Input to the calibration package is completed at the tech support level, with subsequent measurements taken by the operator on a captured frame during the scanning procedure. Four linear measurements can be taken on a single image and viewed during the scan. Single still images with measurement data are then archived for later viewing.

Three operators tested the measurement feature. Each operator was trained in taking linear measurements using the measurement feature. Each operator was asked take 5 different measurements on a target that was positioned in the field of view. The five measurements were repeated 3 times in varying orders. Each operator was able to repeat each linear measurement to within 1.2% of actual dimension with the exception of one measurement where the operator interpreted the measurement endpoints incorrectly, resulting in a 3.5% error. The most experienced operator averaged to within 0.5% of actual dimensions with the most inexperienced operator averaging 1.7% from actual (including the data from the misinterpreted target endpoint scenario).

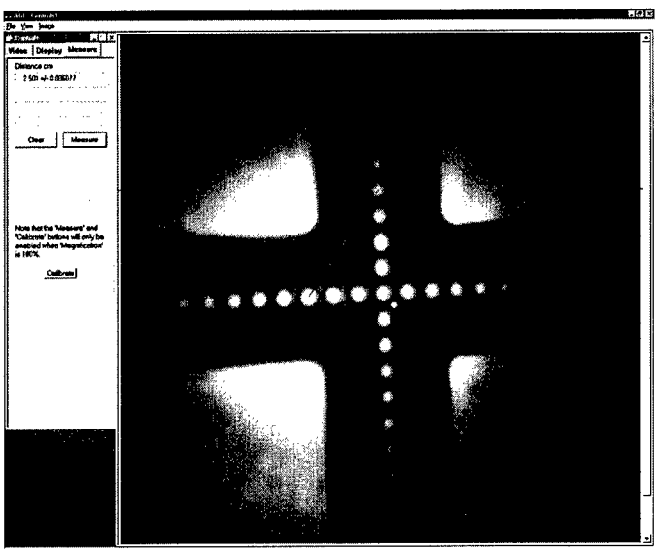

Figure 14a. Measurement control window illustrating the calipers feature

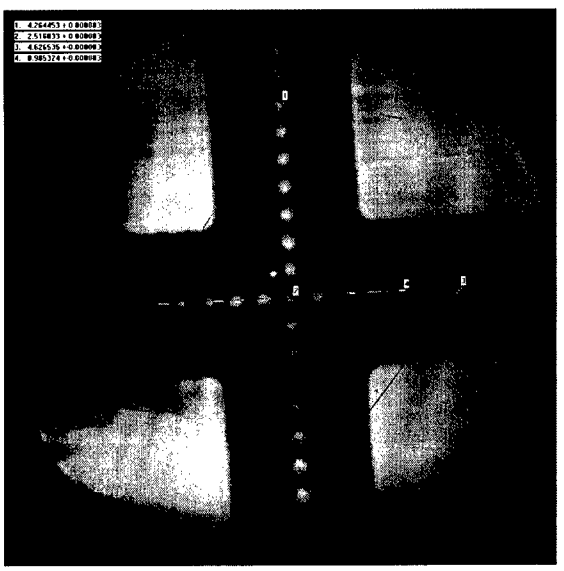

Figure 14b. Archived image with lines and tabulated data shown

A preliminary assessment of the potential for biopsy using Diffractive Energy Imaging was completed in *Task 19.* Simulated biopsies were performed on a Nuclear Associates dual modality biopsy training phantom[11] using a 14 gauge biopsy needle. The phantom was held between the patient compression plates and a target lesion was selected on the image. The biopsy needle was hand held and directed to the target using real-time image guidance. A successfully "biopsy" was completed in every case. After discussion the general consensus was that the technology provided an easy approach to the target in the X-Y plane, but determining the initial approach to the target in the Z focal plane (along the

sound path) was difficult to determine. This indicates clearly that a biopsy feature will require active or passive guidance to the lesion focal plane as a minimum starting point for biopsy. This requirement becomes even more critical when the waterbath is drained to provide dry access to the breast for biopsy, since the edge of the breast will be "lost" in the image (i.e., loss of sound continuity at the edge of the breast). Figure 15 presents 3 still images taken from a captured biopsy cineloop. These are compared to a set of images taken using a high-end reflective ultrasound device. The identical phantom, biopsy gun and needle were used in both cases. The successful results of this task have prompted ADI to incorporate design requirements for a biopsy feature in the pre-production system.

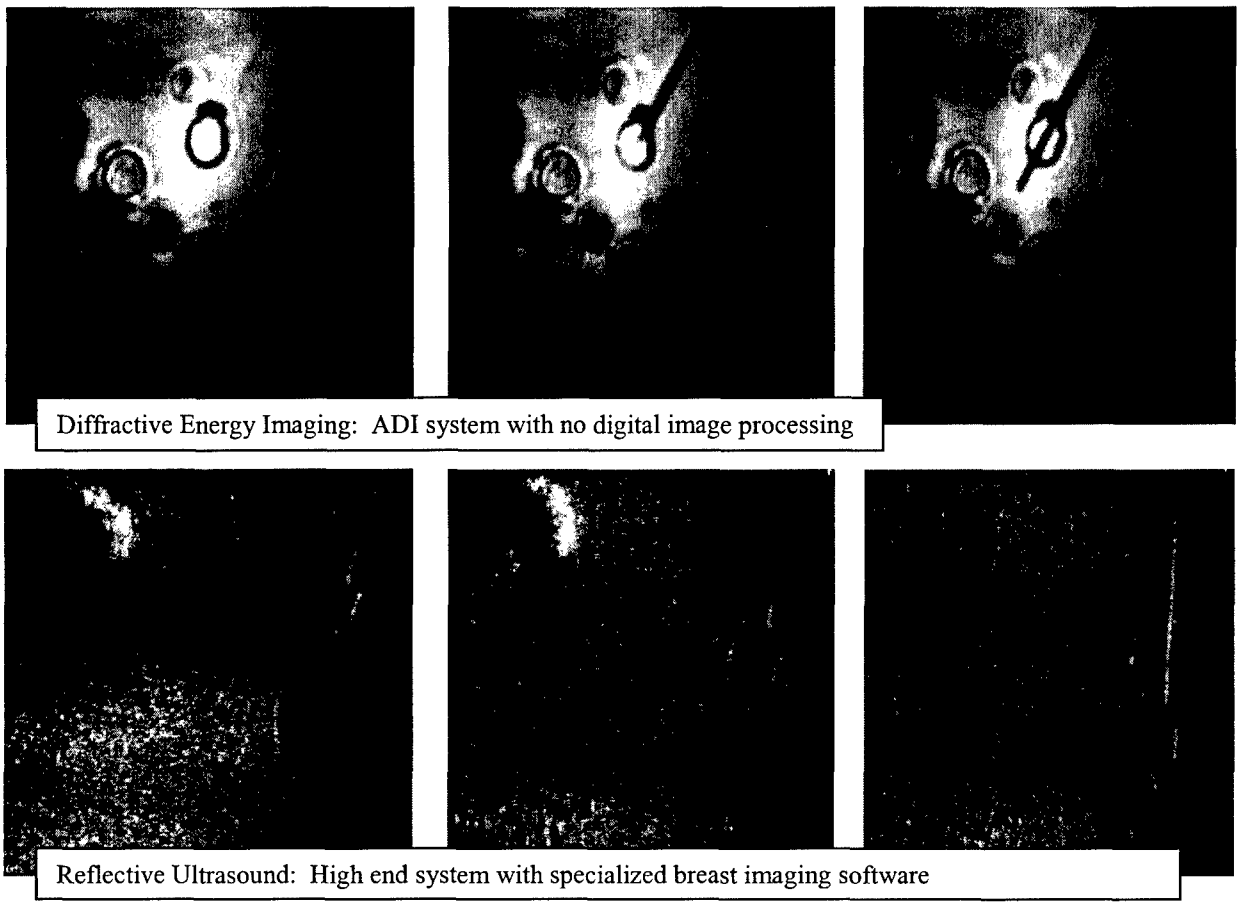


Figure 15. Biopsy Sequence using Identical Biopsy Training Phantom, Biopsy Needle and Biopsy Gun

**KEY RESEARCH ACCOMPLISHMENTS**

- Development of methods and procedures that provide a standard and repeatable method of evaluating image quality
- Development of methods and procedures for collecting breast images.
- Collection and evaluation of breast images on subjects with normal breast anatomy
- Evaluation of the potential of DEI for guided biopsy.

## REPORTABLE OUTCOMES

Abstracts have been submitted to:

1. XXVI International Acoustical Imaging Symposium in Ontario, Canada, Sept 9-12, 2001 - 1 abstract
2. SPIE Medical Imaging Conference in San Diego, CA, Feb 23-28, 2002 - 2 abstracts

## CONCLUSIONS

The development of procedures to determine quantitatively the quality and effectiveness of the image process (from hardware and software development to imaging procedures) is viewed as a key accomplishment in developing utility and value from the results of this program. Standardized metric procedures provide value during not only the current phase, but also to the remainder of this program and to future system development. An integral part of this key accomplishment was the development of a computer database and processes to store and retrieve images for both process evaluations as well as for use in image evaluation and enhancement.

Imaging normal volunteers provided input regarding skin coupling, physical comfort, patient movement, water temperature, compression, and system settings. Results were formalized as part of a breast imaging procedure. The final key accomplishment under this category was the successful implementation of a GUI-based Image Processing tool which will allow the operator to record his or her post-processing settings helping to build a database of post processing parameters to optimize performance.

The third area of accomplishment was in the progress toward evaluating and establishing the DEI Imager as an effective imaging tool for guiding surgical biopsies. Measurement features were tested and proved successful in the biopsy of simulated breast targets. ADI believes that biopsy guidance will become an important application for this device.

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DEPARTMENT OF THE ARMY
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REPLY TO
ATTENTION OF

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1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

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